## REMARKS

In the Office Action of April 15, 2009, Claims 1-5, 8, 12, 13-22, 29-32 and 36 were pending. Claims 6-7, 9-11, 14-21, 23-28, 33-35 and 37-45 were cancelled without prejudice. Claims 22, 29-32 and 36 were withdrawn from further consideration pursuant to 37 C.F.R. §1.142(b). Claims 1-5, 8, 12 and 13 were under examination and were rejected.

This Response addresses each of the Examiners objections and rejections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all the pending claims is respectfully requested.

Claims 1-5, 9, 12 and 13 have been rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent Publication No. 20070059280 to Devalaraja et al. (herein after "the '280 publication"), as purportedly evidenced by the abstracts of Luross, et al., Meisenberg, et al. and Campbell, et al., of record.

Applicants disagree with the Examiner's rejection and submit that in respect to the presently claimed invention, the '280 publication is not enabling. In this regard, Applicants herein provide a copy of U.S. Patent No. 7,108,852 to Devalaraja et al. ("the '852 patent") by way of an Information Disclosure Statement, for the Examiner's consideration. Notably, the specification of the '280 publication is identical to the '852 specification. Accordingly, the record of the '852 patent is relevant here.

A review of the '852 specification demonstrates that the disclosure in respect to the antagonism of G-CSF is certainly no greater than the disclosure respecting the antagonism of M-CSF. Based upon that disclosure, Devalaraja et al. presented claims directed to methods of treating rheumatoid arthritis by administering an antibody to M-CSF during prosecution of the application underlying the '852 patent. These claims were initially rejected by the USPTO as not

enabling. See **Exhibit A**, the Office Action issued on April 7, 2004 in Serial No. 09/885,259. Only a subsequent presentation of actual animal data in well accepted experimental models relative to M-CSF antagonists provided sufficient enablement for the claimed subject matter. See **Exhibit A**, the Response filed by Devalaraja et al. on September 14, 2009 in Serial No. 09/885,259, and the subsequent Office Action dated November 22, 2004.

Applicants respectfully submit that because the disclosure of the '280 publication does not disclose the requisite animal data in respect to the antagonism of G-CSF, the disclosure is not enabling for claims directed to treating arthritis by the administration of G-CSF antagonists. Notably, there is absolutely no justification of record or anywhere, to distinguish the M-CSF antagonist and the relationship in the treatment of arthritis of the '852 patent from the G-CSF antagonist of the '280 publication. The uncertainty in this complex field with respect to the effect of antagonism of a single agent could only be overcome by a specific teaching in the accepted animal model.[1]

Applicants submit that the alleged therapeutic methods disclosed in the '280 publication in relation to G-CSF, are based merely on an observation of the synergistic effect of exogenously added G-CSF on chemokine mediated inflamation. Further, the '280 publication only discloses the potentiating effect of G-CSF on IL-8 mediated chemotaxis. Consider, however, the publication by Keystone, et al. *Current Opinion Rheumatology*, 15:253-258 (2003) (attached hereto as **Exhibit B**) demonstrating that not even direct antagonism of IL-8 by the administration of anti-IL-8 Mab has proven to be effective against RA.[2] Moreover, the '280

1 Applicants observe that the claims are characterized by the transitional phase "consisting of" which distinguishes the plain reading of the '280 publication.

2 The Examiner recognizes that the specification does not need to teach what is old in the art; but those skilled in the art are held to appreciate the unpredictability in the art as well which is also "old" and unreconciled in the art.

publication also discloses experimental data which contradict the potentiating effect of G-CSF on IL-8 mediated chemotaxis.

In this regard, the Examiner is respectfully requested to further consider a Declaration under 37 C.F.R. §1.132 by Dr. Ian Wicks provided herewith as **Exhibit C**. The declaration provides further evidence supporting this conclusion that the '280 publication is not enabling for a claim directed to a method of treating arthritis by the administration of an antagonist of G-CSF.

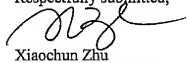
Specifically, Dr. Wicks provides various literature references which establish the relevant state of the art with respect to the understanding by those skilled in the art of the role of G-CSF in immunological studies such as those related to arthritis. Dr. Wicks also discussed the limitations and contradictions of the data disclosed in the '280 publication (see in particular, Paragraph 5 of the Declaration). Dr. Wicks ultimately concludes that the immunological effects of G-CSF and thus the net effect or disease outcome in a conventional animal model of autoimmune mediated diseases was unreasonably unpredictable.

Despite any "proposals" evidenced by the '280 publication, taken as a whole, those skilled in the art, particularly recognizing the level of unpredictability in the art, would conclude that absent data respecting G-CSF antagonist activity in an accepted animal model, the '280 publication is not enabling for a claim directed to a method of treating arthritis solely with an antagonist of G-CSF.

To anticipate, the prior art reference must provide an enabling disclosure. *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985). Because the '280 publication is not enabling with respect to the presently claimed invention, the rejection under 35 U.S.C. §102(e) based on the '280 publication is overcome and withdrawal thereof if respectfully requested.

Thus, in view of the foregoing amendments and remarks, it is firmly believed that the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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